IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. No.:	10/802,315
Confirmation No.:	4928
Filing Date:	03/17/2004
Applicants:	Voit et al.
Art Unit:	2125
Examiner:	Shechtman, Sean P.
Title:	METHOD AND DEVICE FOR OBTAINING ORTHOSIS MODELS

APPEAL BRIEF

Dear Sir:

Please enter the following Appeal Brief in the appeal filed June 6, 2006.

REAL PARTY IN INTEREST

The real party in interest is Orthosolutions oHG, a corporation duly organized and existing under the laws of Germany and having a principal place of business at Simsseestrasse 8, 83022 Rosenheim, Germany, as evidenced at reel 015447, frame 0826.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences to the present application.

STATUS OF CLAIMS

Claims 1 – 10 and 15 – 24 stand rejected. None of the pending claims have been allowed. Claims 11 – 14 and 25 – 27 were cancelled during prosecution. Claims 1, 2, 15, and 16 are the subject of this appeal.

STATUS OF AMENDMENTS

An after-final amendment was submitted on June 5, 2006, and denied entry by the Examiner in an Advisory Action dated June 20, 2006. The after-final amendment proposed amendments to resolve the pending rejections made under 35 U.S.C. § 112 and simplify the issues prior to appeal. The Examiner asserted that the proposed amendments "completely" changed the scope of the claims.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a computer implemented method for producing an orthosis model for a patient. The method includes the step of inputting patient data corresponding to a curvature of the patient's spine with a data input device. (original claim 1; page 10 of the specification, lines 4 - 9; reference numeral 104 in Figure 4, box at twelve o'clock position in Figure 6). The method also includes the step of determining a curvature type of the patient's spine from a predefined number of curvature types stored in a data base with a curvature determination device on the basis of the patient's data. (original claim 1; page 6 of the specification, lines 3 – 5; reference numeral 106 in Figure 4, reference numerals 8 and 12 in Figure 5, box at two o'clock position in Figure 6). The curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine. (page 11 of the specification, lines 32 - 33). The method also includes the step of selecting at least one orthosis model from a predefined number of orthosis models with a model selection device on the basis of the determined curvature type. (original claim 1; page 3 of the specification, lines 8 – 9; reference numeral 110 in Figure 4, reference numeral 10 in Figure 5, box at three o'clock position in Figure 6).

Claim 2 recites an alternative embodiment of the invention recited in claim 1. In the embodiment of the invention recited in claim 2, the inputting step is further defined as inputting at

least one of radiographs, photographs of a back of the patient, status body dimensions o the patient, dynamic body dimensions of the patient, and age of the patient to the data input device. (original claim 2; page 3 of the specification, lines 11 – 33).

Claim 15 recites a computer implemented device for producing an orthosis model for a patient. The computer implemented device includes a data input device for inputting a patient's data corresponding to a curvature of the patient's spine. (original claim 15; page 10 of the specification, lines 4 - 9; reference numeral 104 in Figure 4, box at twelve o'clock position in Figure 6). The computer implemented device also includes a data base containing a number of curvature types and a number of orthosis models. (original claim 15; page 6 of the specification, lines 3 – 5; see unnumbered box to the right of reference numeral 110 in Figure 4, reference numeral 12 in Figure 5, center of the circle in Figure 6). Each curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine and wherein at least one orthosis model is associated with each curvature type. (page 11 of the specification, lines 32 - 33). The computer implemented device also includes a curvature determination device to determine a curvature type on the basis of the patient's data corresponding to the curvature of the patients' spine. (original claim 15; page 6 of the specification, lines 3 – 5; reference numeral 106 in Figure 4, reference numeral 8 in Figure 5, box at two o'clock position in Figure 6). The computer implemented device also includes an orthosis model selection device to select at least one orthosis model from said data base on the basis of the determined curvature type. (original claim 15; page 3 of the specification, lines 8 – 9; reference numeral 110 in Figure 4, reference numeral 10 in Figure 5, box at three o'clock position in Figure 6).

Claim 16 recites an alternative embodiment of the invention recited in claim 15. In the embodiment of the invention recited in claim 16, the data base is further defined as correlating the curvature types with the orthosis models with one of one-valued relationships and many-valued

relationships. The orthosis model selection device is further defined as being operable to select at least one orthosis model on the basis of said relationships. (original claim 16; page 6 of the specification, lines 11 – 16).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Applicants request review of the following seven rejections asserted by the Examiner:

1. Claims 1 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that a spine is not an inherent feature of a patient.

2. Claims 1 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it is not clear how patient data can correspond to a curvature of a patient's spine and correspond to factors independent of the curvature of the patient's spine.

3. Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it is not clear which curvature type is the curvature type.

4. Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that there is insufficient basis for "said inputting step."

5. Claims 1 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it is not clear what is done with a curvature determination device.

6. Claims 1 and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in that it is not clear what is done on the basis of the patient's data.

7. Claims 1, 2, 15, and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,850,836 to Steiger et al. (hereafter "Steiger") in view of U.S. Pat. No. 6,463,351 to Clynch (hereafter "Clynch").

ARGUMENT

1. Claims 1 and 15 are not indefinite; a spine is an inherent feature of a "patient" as that term is used in the claims.

The Examiner asserts that a spine is not an inherent feature of a patient since a veterinarian might consider an invertebrate a patient. Office Action dated March 6, 2006, pages 8 – 9. This rejection is traversed in that one of ordinary skill in the art would not attempt to apply the invention recited in claims 1 and 15 to an invertebrate. The claims recite a method and apparatus for producing an orthosis model for a patient. An "orthosis" is an externally applied device which supports or assists the musculo-neuro-skeletal system.[1] Invertebrates do not have a musculo-neuro-skeletal system.[2] Some invertebrates have a fluid-filled, hydrostatic skeleton, like the jelly fish or worm and other invertebrates have a hard outer shell, like insects and crustaceans.[3] Neither form of invertebrate would require an orthosis model since neither form of invertebrate possess a musculo-neuro-skeletal system.

"Orthosis" can also be defined as relating to the correction of orthopedic maladjustments.[4] Orthopedics is the medical specialty concerned with correction of deformities or

[1] http://en.wikipedia.org/wiki/Orthoses.
[2] http://en.wikipedia.org/wiki/Cuticula_(invertebrate).
[3] http://www.kidport.com/RefLib/Science/Animals/AnimalIndexInv.htm.
[4] Random House Webster's Unabridged Dictionary 1368 (2d ed. 1997).

functional impairments of the skeletal system, especially of the spine.[5] An invertebrate does not have a spine.[6] Therefore, since invertebrates do not have spines, one of ordinary skill in the art would not apply an orthosis model as recited in claims 1 and 15 to an invertebrate.

It is therefore submitted that the rejection is improper; one of ordinary skill in the art would find a spine an inherent feature of a patient requiring an orthosis model.

2. Claims 1 and 15 are not indefinite; the claims do not recite patient data corresponding to factors independent of the curvature of the patient's spine.

The Examiner has rejected claims 1, 4, 15 and 18 as being indefinite in that it is not clear how patient data can correspond to a curvature of a patient's spine and correspond to factors independent of the curvature of the patient's spine. This appeal requests review of the rejection as applied to claims 1 and 15. Since claims 1 and 15 do not recite patient data corresponding to factors independent of the curvature of the patient's spine, it is submitted that the rejection is improper.

3. Claim 1 is not indefinite; the term "curvature type" is recited in the claim in a manner consistent with proper idiomatic English.

Claim 1 recites "determining a curvature type of the patient's spine from a predefined number of curvature types stored in a data base." This phrase relates "curvature type" and "predefined number of curvature types" with respect to one another as species and genus, respectively, and does so in a manner consistent with proper idiomatic English. In other words, the claim recites determining *a* curvature type (singular form of the noun "type") *from* a predefined number of curvature types (plural form of the noun "type"). Claim 1 also recites that the curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of

[5] Id.
[6] http://en.wikipedia.org/wiki/Invertebrate.

curvature of the abstract spine. As a result, the curvature type determined from the predefined number of curvature types will be defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine.

The focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. M.P.E.P. 2173.02. In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. Id. If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office action. Id.

In the present matter, the Examiner has not provided an analysis as to why the phrases "curvature type" and "predefined number of curvature types" are vague and indefinite. As set forth above, the phrases are used properly with respect to idiomatic English. It is also noted that both "curvature type" and "predefined number of curvature types" were recited in the original claims and were not rejected in the first office action under § 112. It is further noted that claim 15 also recites "curvature type" and "number of curvature types" but does not stand rejected as being indefinite for this reason.

In view of these considerations, it is submitted that the rejection is without merit.

4. Claim 2 is not indefinite; there is antecedent basis for the inputting step.

Claim 2 depends from claim 1 and the first step of claim 1 is an inputting step. It is therefore submitted that the rejection is improper.

5. Claims 1 and 15 are not indefinite; the claims recite that the curvature determination device determines a curvature type.

Claims 1 and 15 both recite, unambiguously, that the curvature determination device determines a curvature type. Claim 1 recites "determining a curvature type of the patient's spine from a predefined number of curvature types stored in a data base with a curvature determination device." Claim 15 recites "a curvature determination device to determine a curvature type."

The Examiner states "it is unclear what is done 'with a curvature determination device', - determining a curvature type of the patient's spine or storing of a predefined number of curvature types in a database?" March 6 Office Action, page 4. The basis of the Examiner's query is not apparent from the written record of this application; neither claim 1 nor claim 15 associates "storing of a predefined number of curvature types in a database" with the curvature determination device. Furthermore, none of the remaining claims, nor the specification, make such as an association. It is therefore submitted that the Examiner's rejection is without merit.

6. Claims 1 and 15 are not indefinite; the claims recite that the patient's data is the basis for the determination of the curvature type.

Claims 1 and 15 both recite, unambiguously, that the patient's data is the basis for the determination of the curvature type. Claim 1 recites "determining a curvature type of the patient's spine from a predefined number of curvature types stored in a data base with a curvature

determination device on the basis of the patient's data." Claim 15 recites "a curvature determination device to determine a curvature type on the basis of the patient's data."

The Examiner states "it is unclear what is done 'on the basis of the patient's data', - determining a curvature type of the patient's spine or storing of a predefined number of curvature types in a database?" March 6 Office Action, page 4. The basis of the Examiner's query is not apparent from the written record of this application; neither claim 1 nor claim 15 associates "storing of a predefined number of curvature types in a database" with the patient's data. The term "storing" is not used in either claim 1 or 15. It is therefore submitted that the Examiner's rejection is without merit.

7. Claims 1 and 15 are patentable over the prior art of record on several grounds.

The Examiner has rejected claims 1 – 10 and 15 – 24 as being unpatentable over Steiger in view of Clynch. This appeal requests review of the rejection as applied to claims 1, 2, 15, and 16.

A. The prior art of record does not teach or suggest the second step of claim 1:

Steiger discloses a method of determining vertebral morphometry. In the method, a plurality of points is placed on an image of the patient's vertebrae. Each vertebra is considered individually by an operator. Points are placed on anterior, mid, and posterior positions of the inferior and superior endpoints of the individual vertebrae. The points are used to calculate anterior, mid, and posterior heights of the vertebral bodies. These dimensions can be useful in determining bone density as well as determining if a fracture of the vertebrae has occurred.

Steiger fails to teach or suggest determining a curvature type from a predefined number of curvature types stored in a data base for two reasons. First, the location of each point is

chosen ad hoc by an operator. The operator does not determine *a* curvature type *from* a predefined number of curvature types stored in a data base. See column 6, lines 62 – 65; column 1, lines 61 – 64; and column 3, lines 65 – 66. Furthermore, Steiger does not teach or suggest extending a curve between all the points chosen by the operator. However, even if such a teaching were found in Steiger, the curve would be the result of a series of ad hoc choices made by the operator.

Second, claim 1 recites that each of the curvature types stored in the data base is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine. Steiger does not teach or suggest a data base containing a predefined number of curvature types so defined. Steiger discloses a system that may suggest individual point placement based on normal vertebral anatomy. However, normal vertebral anatomy does not define a curvature requiring an orthosis model. In addition, the single example of individual points associated with normal vertebral anatomy does not anticipate or render obvious a predefined number of *curvature types* as recited in claim 1.

Clynch does not overcome the deficiencies of Steiger. Clynch discloses a method for producing an orthotic structure wherein a physical model is formed over a patient's body, shipped to a manufacturing facility, and scanned for conversion into machine control code. The physical model created by the Clynch process is not a curvature type, but rather a temporary orthosis model for treatment of the patient's curvature type. In addition, the physical model is not determined from a predefined number of curvature types stored in a data base. The physical model is built "from scratch."

It is therefore submitted that claim 1 patentably defines over the references and is in suitable condition for allowance. Claim 2 depends from claim 1 and is therefore allowable by dependency.

B. The prior art of record does not teach or suggest the third step of claim 1:

Steiger does not disclose any form of orthosis models, much less selecting at least one orthosis model from a predefined number of orthosis models. The teachings of Steiger are not directed toward treating spinal curvature, but to vertebrate morphometry.

Clynch does not overcome the deficiency of Steiger. Clynch fails to teach or suggest selecting an orthosis model from a predefined number of orthosis models. Clynch teaches a system for producing an orthotic structure in a customized process; each orthotic structure is built without reference to other models. A physical model is crafted around the body of a patient, shipped to a manufacturer, and scanned into machine control code.

It is further submitted that Clynch teaches away from the invention recited in claim 1. The present application identifies a process substantially similar to the process disclosed by Clynch at page 1, line 28 through page 2, line 11. The present application disparages such a process. Claim 1 recites a method operable to standardize orthosis model production by capitalizing on the resources expended to create prior orthosis models. One of ordinary skill in the art would not look to the individual piece production process disclosed by Clynch, from any primary reference, to arrive at the invention recited in claim 1.

It is therefore submitted that claim 1 patentably defines over the references and is in suitable condition for allowance. Claim 2 depends from claim 1 and is therefore allowable by dependency.

C. The prior art of record does not teach or suggest the second element of claim 15:

Neither Steiger nor Clynch teach or suggest a data base containing a number of curvature types and a number of orthosis models wherein each curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract

spine and wherein at least one orthosis model is associated with each curvature type. As set forth above in Section 7A, Steiger teaches a system that may contain individual points corresponding to normal geometry of single vertebra. Individual points do not define a curvature and normal vertebra geometry does not define a curvature requiring treatment with an orthosis model. As set forth above in Section 7B, Steiger does not disclose any form of orthosis models. The teachings of Steiger are not directed toward treating spinal curvature, but to vertebrate morphometry. As a result, Steiger does not teach or suggest a data base containing a number of curvature types and a number of orthosis models.

Clynch does not overcome the deficiencies of Steiger. Clynch discloses a system of individual piece production for manufacturing orthotic structures. Clynch does not teach or suggest a data base containing a number of curvature types and a number of orthosis models.

It is therefore submitted that claim 15 patentably defines over the references and is in suitable condition for allowance. Claim 16 depends from claim 15 and is therefore also allowable by dependency.

D. The prior art of record does not teach or suggest the fourth element of claim 15:

Neither Steiger nor Clynch teach or suggest an orthosis model selection device to select at least one orthosis model from the data base on the basis of the determined curvature type. Steiger does not disclose orthotic models and therefore does not teach or suggest a selection device to select at least one orthosis model from the data base on the basis of the determined curvature type. Clynch is directed to a system of individual piece production for manufacturing orthotic structures and therefore does not teach a selection device to select at least one orthosis model from a data base containing a number of orthosis models.

It is therefore submitted that claim 15 patentably defines over the references and is in suitable condition for allowance. Claim 16 depends from claim 15 and is therefore also allowable by dependency.

E. The prior art of record does not teach or suggest the features recited in claim 16:

Claim 16 recites that the database correlates the curvature types with said orthosis models with one of one-valued relationships and many-valued relationships. Claim 16 also recites that the orthosis model selection device is operable to select at least one orthosis model on the basis of the relationships. Steiger does not disclose a data base containing a number of curvature types and a number of orthosis models and therefore does not teach or suggest a data bases operable to correlate curvature types with orthosis models. Similarly, Clynch does not disclose a data base containing a number of curvature types and a number of orthosis models and therefore does not teach or suggest a data bases operable to correlate curvature types with orthosis models.

It is therefore submitted that claim 16 patentably defines over the references and is in suitable condition for allowance, in addition to being allowable by dependency from claim 15.

CONCLUSION

For the reasons stated above, it is respectfully submitted that Appellants' invention as set forth in claims 1, 2, 15, and 16 patentably define over the cited references for the reasons set forth above. It is therefore respectfully submitted that the Examiner's final rejections of claims 1, 2, 15, and 16 are erroneously based and reversal of the rejections is respectfully requested.

No oral hearing is requested.

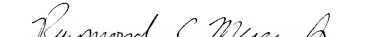
This Appeal Brief is being filed through EFS-Web and payment for $500 to cover the Appeal Brief filing fee is being concurrently authorized. If additional fees are incurred because

of this Appeal Brief and not included, the Commissioner is authorized to charge said additional fees, as well as credit any overpayments, to Deposit Account No. 04-1061 of Dickinson Wright, PLLC.

Respectfully submitted,

DICKINSON WRIGHT PLLC

July 10, 2006



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CLAIMS APPENDIX

1. (Previously Presented) A computer implemented method for producing an orthosis model for a patient comprising the steps of:

inputting patient data corresponding to a curvature of the patient's spine with a data input device;

determining a curvature type of the patient's spine from a predefined number of curvature types stored in a data base with a curvature determination device on the basis of the patient's data wherein the curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine; and

selecting at least one orthosis model from a predefined number of orthosis models with a model selection device on the basis of the determined curvature type.

2. (Previously Presented) The computer implemented method according to claim 1, wherein said inputting step is further defined as:

inputting at least one of radiographs, photographs of a back of the patient, status body dimensions o the patient, dynamic body dimensions of the patient, and age of the patient to the data input device.

3. (Previously Presented) The compute implemented method according to claim 1 wherein said selecting step is further defined as:

selecting a plurality of orthosis models in dependence on the patient's data.

4. (Previously Presented) The computer implemented method according to claim 1 further comprising the step of:

obtaining the patient's data corresponding to factors independent of the curvature of the spine.

5. (Previously Presented) The computer implemented method according to claim 1 further comprising the step of:

modifying the selected orthosis model in response to the patient's data corresponding to factors independent of the curvature of the spine.

6. (Previously Presented) The computer implemented method according to claim 5 further comprising the steps of:

adding the modified orthosis model to the predefined number of orthosis models in the data base.

7. (Previously Presented) The computer implemented method according to claim 6 further comprising the step of:

producing an orthosis mould according to one of the selected and the modified orthosis model.

8. (Previously Presented) The computer implemented method according to claim 7 further comprising the step of:

refinishing the produced orthosis mould.

9. (Previously Presented) The computer implemented method according to claim 9 further comprising the steps of:

reading in the refinished orthosis mould with a reading-in device as an orthosis model; and

adding the orthosis model read-in during said reading in step to the data base of having the predefined number of orthosis models.

10. (Previously Presented) The computer implemented method according to claim 1 wherein said determining step includes the step of:

assigning a new curvature type based on the patient's data; and

adding the new curvature type to the predefined number of curvature types in the data base.

Cancel claims 11-14.

15. (Previously Presented) The computer implemented device for producing an orthosis model, comprising:

a data input device for inputting a patient's data corresponding to a curvature of the patient's spine;

a data base containing a number of curvature types and a number of orthosis models wherein each curvature type is defined by a number of points of deflection of an abstract spine and one or more directions of curvature of the abstract spine and wherein at least one orthosis model is associated with each curvature type;

a curvature determination device to determine a curvature type on the basis of the patient's data corresponding to the curvature of the patients' spine; and

an orthosis model selection device to select at least one orthosis model from said data base on the basis of the determined curvature type.

16. (Previously Presented) The computer implemented device according to claim 15, wherein said data base is further defined as correlating said curvature types with said orthosis models with one of one-valued relationships and many-valued relationships, and wherein said orthosis model selection device is further defined as being operable to select at least one orthosis model on the basis of said relationships.

17. (Previously Presented) The computer implemented device according to claim 16, wherein said orthosis model selection device selects at least two orthosis models on the basis of said relationships, and wherein said orthosis model selection device selects one orthosis model from said at least two orthosis models in dependence on the patients' data corresponding to a curvature of the patient's spine.

18. (Previously Presented) The computer implemented device according to claim 17, further comprising:

a device for obtaining the patient's data corresponding to factors independent of the curvature of the spine, wherein the device inputs the obtained patient's data into said data input device.

19. (Previously Presented) The computer implemented device according to claim 18, further comprising:

a data processing system operable to modify the selected orthosis model according to the patient's data corresponding to factors independent of the curvature of the spine.

20. (Previously Presented) The computer implemented device according to claim 19 wherein said data processing system adds the modified orthosis model to the predefined number of orthosis models in said data base.

21. (Previously Presented) The computer implemented device according to claim 20 wherein said data processing system modifies the curvature types and orthosis models in said data base.

22. (Previously Presented) The computer implemented device according to claim 21, further comprising:

a shaping device for producing an orthosis mould according to one of the selected and modified orthosis model.

23. (Previously Presented) The device according to claim 22, further comprising:

a reading-in device for reading in an orthosis mould and adding an orthosis model according to the read-in orthosis mould to the number of orthosis models in the data base.

24. (Previously Presented) The computer implemented device according to claim 23, wherein said data processing system determines a new curvature type from the patient's data corresponding to a curvature of the patient's spine and adds the new curvature type to the predefined number of curvature types in said data base.

Cancel claims 25 - 27.

EVIDENCE APPENDIX

No evidence is submitted with this appeal brief; this appeal brief relies on the file wrapper of the application.

RELATED PROCEEDINGS APPENDIX

There are no related appeals or interferences to the present application.